

**IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF WEST VIRGINIA
AT CLARKSBURG**

MERCK SHARP & DOHME LLC,

Plaintiff,

v.

MYLAN PHARMACETICALS INC.,

Defendant.

C.A. No. 1:19-cv-101(IMK)

**NOTICE OF SETTLEMENT ON APPEAL AND JOINT MOTION FOR AN
INDICATIVE RULING TO EFFECT TERMS OF THE SETTLEMENT.**

The parties provide notice of their settlement of all matters in dispute in the above-captioned case, subject to the Court's willingness to take certain action necessary to effectuate the settlement. Specifically, the terms of the parties' settlement necessitate modification of the Court's final judgment entered on September 21, 2022, (ECF No. 194), and amended on September 29, 2022, (ECF No. 197). The needed changes are contained in a Proposed Stipulated Modified Amended Final Judgment, attached hereto as **Exhibit A**.

This case is currently on appeal to the United States Court of Appeals to the Federal Circuit. As a result, this Court is presently divested of jurisdiction to take any action to help effectuate the parties' settlement. Rule 62.1 of the Federal Rules of Civil Procedure make provision for settlements occurring during an appeal that may require agreed modification of a judgment. Pursuant to that rule, the parties jointly request an indicative ruling that the Court will enter the Proposed Stipulated Modified Amended Final Judgment, upon remand from the Federal Circuit. The Court's entry of an indicative ruling that the Court will modify the judgments as requested will allow the parties' settlement agreement to go forward. Permitting the settlement agreement to proceed will conserve the resources of the parties and the courts, and will end any possibility of

further proceeding in this court due to the pending appeal. Other district courts have granted very similar relief under very similar circumstances. *E.g., Janssen Prod., L.P. v. Lupin Ltd.*, 2016 WL 3392291, at *3 (D.N.J. June 15, 2016). Once this Court enters the requested indicative ruling, the parties will seek remand pursuant to Federal Rule of Appellate Procedure 12.1, so that this Court may enter the Proposed Stipulated Modified Amended Final Judgment. At that point, Mylan will voluntarily dismiss its appeal.

BACKGROUND

The underlying suit is a patent case concerning U.S. Patent No. 7,326,708 (“the ’708 patent”) and U.S. Patent No. 8,414,921 (“the ’921 patent”). These patents cover Merck’s diabetes drugs Januvia® (sitagliptin) and Janumet® (sitagliptin/metformin). Mylan submitted abbreviated new drug applications for generic sitagliptin and sitagliptin/metformin products, and filed Paragraph IV certifications on the ’708 and ’921 patents. Merck responded by bringing this lawsuit against Mylan in May 2019.

The parties proceeded with a four-day bench trial in December 2021. In September 2022, this Court issued a post-trial opinion concluding that Mylan infringed both patents and that both were valid. (ECF No. 193.) The Court subsequently entered final judgment in Merck’s favor (ECF Nos. 194 and 197), which ordered in relevant part that:

“Pursuant to 35 U.S.C. § 271(e)(4)(A), the effective date of any final approval of ANDA No. 202473 shall be a date that is not earlier than the latest date of expiration of U.S. Patent No. 7,326,708, including any extensions or additional periods of exclusivity”; and

“Pursuant to 35 U.S.C. § 271(e)(4)(A), the effective date of any final approval of ANDA No. 202478 shall be a date that is not earlier than the latest date of expiration of U.S. Patent Nos. 7,326,708 and 8,414,921, including any extensions or additional periods of exclusivity.”

(ECF No. 197.)

Mylan took a timely appeal of the Court's final judgment. At that point, jurisdiction transferred from this Court to the Federal Circuit. *Griggs v. Provident Consumer Disc. Co.*, 459 U.S. 56, 58 (1982). The parties continued settlement discussions during the pendency of Mylan's appeal. They reached a final settlement of their dispute on March 14, 2023.

The full terms of the settlement are confidential. But, as is relevant here, the parties agreed that Mylan shall have a license to obtain an effective date for, and begin to market and sell the products subject to, Mylan's Abbreviated New Drug Application Nos. 202473 and 202478 on specific dates prior to the expiration of the relevant patents-in-suit. Effecting the terms of this agreement necessitates modification of the Court's Amended Final Judgment, which bars Mylan from obtaining an effective date for, and from beginning to market and sell the products subject to, its ANDAs until the expiration of the relevant patents-in-suit.

Simultaneously with the filing of this motion, the parties jointly moved the Federal Circuit for a 60-day stay of the appellate action, so that the parties may seek the indicative ruling requested herein.

ARGUMENT

Pursuant to Federal Rule of Civil Procedure 62.1, this Court may consider a motion "for relief that the court lacks authority to grant because of an appeal that has been docketed and is pending." If it agrees the relief would be appropriate, it may "state either that it would grant the motion if the court of appeals remands for that purpose..." Fed. R. Civ. P. 62.1(c). Entry of an indicative ruling that the Court would modify its judgment to effectuate a settlement reached on appeal is a well-accepted use of Rule 62.1. *E.g., Resqnet.com, Inc. v. Lansa, Inc.*, 481 F. App'x 615, 616 (Fed. Cir. 2012); *Ameranth, Inc. v. Menusoft Sys. Corp.*, 463 F. App'x 920 (Fed. Cir. 2012); *Acoustic Techs., Inc. v. Itron, Inc.*, 428 F. App'x 996 (Fed. Cir. 2011). In fact, the Advisory

Committee Notes to Rule 62.1 outright say that the rule is meant to facilitate “Rule 60(b) motion to vacate [or, in this case, modify] a judgment that is pending on appeal.”

This Court may grant the relief requested through the indicative ruling under Federal Rule of Civil Procedure 60(b), which provides that “[o]n motion and just terms, the court may relieve a party . . . from a final judgment, order, or proceeding.” Here, either Rule 60(b)(5) or 60(b)(6) would authorize modification of the judgment.

Under Rule 60(b)(5), a district court may modify a final judgment where “applying [the final judgment] prospectively is no longer equitable.” Fed. R. Civ. P. 60(b)(5). Parties seeking modification of a final judgment pursuant to this provision must demonstrate that a “significant change in circumstances” warrants revision of the judgment. *Rufo v. Inmates of Suffolk Cty. Jail*, 502 U.S. 367, 383 (1992). Once the movant has met that burden, the Court should then “consider whether the proposed modification is suitably tailored to the changed circumstance.” *Id.*; *Agostini v. Felton*, 521 U.S. 203, 215 (1997) (applying *Rufo* standards to modifications of injunctions in final judgments).

The circumstances here satisfy the Rule 60(b)(5) standard. There has been a significant change in circumstances since this Court issued its judgment—the parties have settled. The settlement necessitates the requested modification to the judgment; without it, the parties will not be able to realize one of the key features of that settlement. *See Janssen Prod., L.P.*, 2016 WL 3392291, at *3 (granting a motion very similar to this one and observing “it would be inequitable for the Court to refuse to modify a judgment preventing the parties from carrying out this settlement”). Indeed, if the Court refuses the modification, the settlement provides that the parties will return to active litigation in the Federal Circuit.

Further, the requested modifications to the judgment are suitably tailored to the change in circumstance. Indeed, they are very modest. They merely note that nothing prevents the U.S. Food and Drug Administration from granting final approval to ANDA Nos. 202473 and 202478 while maintaining a restriction on Mylan's ability to engage in the commercial manufacture, use, offer to sell, or sale within the United States, or importation into the United States (to the extent such activities are not protected by 35 U.S.C. § 271(e)(1)), of the drug products that are the subject of Mylan's ANDA Nos. 202473 and 202478 except as agreed to by the parties pursuant to the Settlement Agreement.

Critically, the requested relief would not wholesale reverse this Court's judgment nor vacate its post-trial opinion. It simply provides a modification to the existing terms of the judgment, which reflects the bargained-for terms of the parties' settlement. *Janssen Prod., L.P.*, 2016 WL 3392291, at *4 (noting that the proposed order "leaves intact the Court's findings of fact and law," "does not 'discard' the Court[s] previous decision," and "simply allows the settling parties to comply with the terms of the settlement agreement").

Alternatively, relief would be appropriate under Rule 60(b)(6), which allows the Court to amend or modify a final judgment "for any other reason that justifies relief." *Kirby Forest Indus., Inc. v. United States*, 467 U.S. 1, 18 (1984). Here, the parties' settlement agreement expressly contemplates amendment of the judgment, which is necessary to effect the terms of their bargain. District courts routinely find that effectuating a settlement agreement is a clear "reason that justifies relief" in the form of modifying (or even outright vacating) a judgment. *Janssen Prod., L.P.*, 2016 WL 3392291, at *2-3; *see also Tommy Hilfiger Licensing, Inc. v. Costco Cos., Inc.*, 2002 WL 31654958, at *2-3 (S.D.N.Y. Nov. 25, 2002) (issuing "indicative ruling" whereby the court, upon remand, would vacate judgment in light of settlement conditioned upon vacatur of

judgment); *Freedom Wireless, Inc. v. Bos. Commc'ns Grp., Inc.*, 2006 WL 4451477, at *1-2 (D. Mass. Oct. 11, 2006) (similar).

Regardless of which avenue the Court would be inclined to take, modifying the judgment as requested by the parties would serve the public interest. The amendments would allow the parties to complete a settlement that brings to an end litigation that first began in 2019. It would also conserve judicial resources. It would allow Mylan to terminate its pending appeal, thereby sparing the Federal Circuit from reviewing and ruling upon the case. And it would also spare this Court from further action on remand, should Mylan succeed on appeal.

CONCLUSION

The Court should issue an indicative ruling stating that it would enter the Proposed Stipulated Modified Amended Final Judgment upon remand from the Federal Circuit.

[Signature block follows.]

Dated: March 16, 2023

Respectfully submitted,

/s/ Steven R. Ruby (with permission)

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